

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7053GB448260306

Final Assessment Report no.
7053AU16F

Effective date
2026-03-06

Expiry date
2030-06-27

This is to certify that the quality system of

edelweiss dentistry products gmbh

Dammstraße 68, 6922 Wolfurt, Austria

SRN: AT-MF-000005413

For design & development, manufacturing and final product inspection/testing of
Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded
in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2026-03-06



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Markus Bianchi
Certification Body Operations

The certificate is only valid when provided entirely with
all of its pages. To verify the validity of this certificate,
contact medcert-info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. 820111 EN Rev 9 2026.02.24

NOTIFIED BODY 0482: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



DNV

Certificate no.: 7053GB448260306
Place and date: Hamburg, 2026-03-06

Sites covered by this certificate

edelweiss dentistry products gmbh, Dammstraße 68, 6922 Wolfurt, Austria

Preceding certificate

| Certificate no. | Issue date | Identification of changes |
|-----------------|------------|---|
| 7053GB448260123 | 2026-01-23 | WO-015193 Adding class IIa, MDN 1103, EMDN Q0106 |





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Products covered by this certificate

Class IIa medical devices

| Category | EMDN code | Medical devices/groups of medical devices |
|----------|-----------|---|
| MDN 1103 | Q0102 | DEVICES FOR PROSTHETIC DENTISTRY |
| MDN 1103 | Q0106 | MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES |
| MDN 1209 | Q0106 | MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES |

